

## **REMARKS**

### **Status of the Claims**

Claims 1-2, 4-10, and 15-25 are pending in the application. Claims 16-25 were previously withdrawn without prejudice to further prosecution as being drawn to non-elected subject matter and are herein cancelled without prejudice.

Claim 1 has been amended herein to remove language reciting at least 70% amino acid sequence identity. Accordingly, claims 12-14 have been canceled herein without prejudice. Support for this amendment can be found in the specification at, for example, the paragraph spanning pages 9 and 10. Claim 15 has been amended for clarity, precision, and consistency of claim language. As amended, claim 15 recites “the particle according to claim 1.” No new matter has been added by way of these amendments.

These claim amendments were not presented earlier as Applicants firmly believed that the previously presented claims recited patentable subject matter. Entry of these claim amendments into this application is respectfully requested in order to place the application in condition for allowance or in better condition for appeal.

Claims 1-2, 4-10, and 15 are now pending in the application and stand rejected. In light of the above amendments and the remarks below, Applicants respectfully request reconsideration and allowance of the pending claims. The Examiner’s comments in the Office Action are addressed below in the order set forth therein.

### **The Objection to the Claims Should Be Withdrawn**

Claim 15 was objected to for containing informalities. As suggested by the Examiner, Applicants have herein amended claim 15 to recite “the particle according to claim 1.” Applicants respectfully submit that amended claim 15 is clear and consistent with the other claims. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection to claim 15.

The Rejection of the Claims Under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

*Written Description*

Claims 1-2, 4-10, and 12-13 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in a manner that conveys to one having ordinary skill in the art that, at the time the application was filed, Applicants were in possession of the claimed invention. Specifically, the Examiner alleged that the claims are directed to a genus that is highly variable. Applicants note that claims 12 and 13 have been canceled without prejudice. This rejection is respectfully traversed with respect to the amended claims.

Without acquiescing to the Examiner's rejection, and solely to further prosecution, Applicants have herein amended independent claim 1 to remove language reciting at least 70% amino acid sequence identity to amino acid sequences SEQ ID NOS:1, 2, and 8. As amended, claim 1 is directed to lipoprotein particles comprising a peptide component, wherein the binding sequence of the peptide component is the amino acid sequence of SEQ ID NO:1, 2, or 8.

Applicants respectfully submit that the specification provides adequate written description of the claimed genus which, contrary to the Examiner's allegation, is not highly variable. For example, the specification provides amino acid sequences of the three Apo B binding sites and describes exemplary peptides comprising the Apo B binding site sequences of the claimed genus. See, for example, Figure 7. The specification also provides that the amino acid sequence can comprise any one, two, or all of the Apo B binding site sequences of the claimed genus in the same peptide or in the form of dimers or in different peptides. See, for example, the paragraph spanning pages 9 and 10. Consequently, the skilled artisan can immediately envision the detailed chemical structure of the peptide binding sequences encompassed by claim 1 and claims depending therefrom. Therefore, one having ordinary skill in the art would have recognized that, at the time of filing of the application, Applicants were in possession of the presently claimed subject matter.

In view of the foregoing remarks and all of the arguments of record, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims as lacking written description under 35 U.S.C. § 112, first paragraph.

*Enablement*

Claims 1-2 and 4-13 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to reasonably provide enablement for a person skilled in the art to make the invention commensurate in scope with the claims. Specifically, the Examiner alleged that the specification do not provide a correlation between function and structure, and fails to demonstrate or describe the genus of peptides encompassed by the claims. Furthermore, the Examiner alleged that, while being enabling for the peptides set forth as SEQ ID NOS:3, 4, 5, 6, 7, and 9, the specification does not enable any peptide fragment of those sequences. This rejection is respectfully traversed with respect to the amended claims.

As described above, Applicants have herein amended independent claim 1 to remove language reciting at least 70% amino acid sequence identity to amino acid sequences SEQ ID NOS:1, 2, and 8. As amended, claim 1 is directed to particles comprising a peptide component, wherein the binding sequence of the peptide component is the amino acid sequence of SEQ ID NO:1, 2, or 8. Accordingly, the claims encompass peptides SEQ ID NOS:3, 4, 5, 6, 7, and 9 which comprise the Apo B binding site sequences of the claimed genus. As acknowledged by the Examiner, these peptides are enabled by Applicants' specification.

Applicant reminds the Examiner that the Federal Circuit has stated that the test for undue experimentation is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. *Johns Hopkins University v. Cellpro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998). Applicants contend that the level of experimentation required to practice the presently claimed invention would not be undue. One of skill in the art could readily make particles falling within the full scope of amended claim 1 and claims depending therefrom for use in accordance with the

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claimed invention without undue experimentation. The experimentation involved to produce these particles would have been well within the skill of those in the art and, thus, would have been routine.

In view of the foregoing remarks and all of the arguments of record, Applicants respectfully submit that the present specification enables one of skill in the art to make and use the invention as set forth in the present claims without undue experimentation. Accordingly, this enablement rejection should be withdrawn.

### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicant respectfully submits that the rejections of the claims under 35 U.S.C. § 112 are overcome and that this application is now in condition for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

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It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefor (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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